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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-----------------------|
| 10/634,692 | 08/05/2003 | Paul Burnett | PRD-0023NP | 7576 |
| 27777 | 7590 | 05/26/2006 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | | SRIVASTAVA, KAILASH C |
| | | ART UNIT | | PAPER NUMBER |
| | | 1655 | | |

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/634,692 | BURNETT ET AL. | |
| | Examiner | Art Unit | |
| | Dr. Kailash C. Srivastava | 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 March 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,14-16,19,20 and 34 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 3-13,17,18 and 21-33 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/19/2004.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

1. Applicants' responsive amendment filed 9 March 2006 in response to Office Action of 09 February 2006 is acknowledged and entered
2. To ensure that all papers filed in a response remain together and for expedient communication to a response /amendment filed to an Office Action, Examiner will very much appreciate and recommends that in response to this Office Action, applicants label the header at each page of said response with application Serial number, filing date, applicants' name and Attorney's Docket number. This practice immensely minimizes the papers lost during transaction/transmission and facilitates examination.

CLAIMS STATUS

3. Claims 1-34 are pending.

Restriction/Election

4. Applicants' response and election with traverse of Group II, Claims 4-13, 17-18 and 21-33 for prosecution filed 09 March 2006 in response to Election/Restriction requirement in Office Action of 09 February 2006 is acknowledged and entered. Applicants' traversal is on the grounds that the inventions grouped as I-VII in the Office Action cited *supra* can be searched without any "serious" burden to the Examiner.

Examiner has fully and carefully considered applicants' arguments filed 09 March 2006. Examiner does not find applicants' said arguments persuasive because of the reasons of record on pages 3-4 in Office Action cited *supra*. Examiner has clearly stated in said Office action, the status is different because each of the Groups are in separate Class/subclass. In addition, the search for each of the distinct inventions of Groups I-VII is not co-extensive particularly with regard to the literature search, because each group requires a different search strategy with different key words for each of the inventive groups cited in Office Action mailed 09 February 2006. In addition, the burden lies not only in the search of U.S. patents, burden also lies in the

- i. search for non-patent scientific and commercial literature;
- ii. foreign patents;
- iii. examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement.

Thus, clearly different searches and issues are involved with each group. Moreover, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious

another group. Finally, the condition for patentability is different in each case. For these reasons, the restriction requirement is still deemed proper, is adhered to and is made FINAL.

Accordingly, Claims 1-2, 14-16, 19-20 and 34 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP §821.03. Examiner suggests that to expedite prosecution, the non-elected claims cited *supra* (i.e., Claims 1-2, 14-16, 19-20 and 34) be canceled in response to this Office action.

5. Claim 3 as linking Claim and Claims 4-13, 17-18 and 21-33 are examined on merits.

Priority

6. Applicants' claim for domestic priority under 35 U.S.C. § 119(e) to U.S. Provisional Applications, 60/401,156 filed 05 August 2002 and 60/434, 917 filed 20 December 2002 is acknowledged.

Information Disclosure Statement

7. Applicants' Information Disclosure Statement (i.e., IDS) filed 19 November 2004 is acknowledged, has been made of record and considered.

Objection To Specification

8. The specification is objected to because the applicants do not cite application priority data at Line one of first page of specification. Applicants are required to indicate at first line of the first page of the specification that the instant application Claims priority to provisional U.S. applications, as follows.

This application Claims Priority to U.S. Provisional Applications Serial Nos., 60/401,156 filed 05 August 2002 and 60/434, 917 filed 20 December 2002

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

11. Claims 4-13, 17-18 and 21-33 are rejected under 35 U.S.C. § 103 (a) as obvious over combined teachings from Wong et al. (U.S. Patent 5,843,741) in view of Casnig (U.S. Patent 5,134,070)

Claims 4-13, 17-18 and 21-33 recite a method to identify the biological activity of a compound, wherein a compound is put together with a cell suspended in a liquid and an electric voltage through an electrode is passed into the microwells where the cells suspended in said liquid are present. The cells and the electrode are in place with an electrically conductive transparent material comprising among others zinc oxide or a dielectric, e.g., silicon dioxide. The cell is eukaryotic or prokaryote and signals are obtained through optical signal catching markers in to an imaging system. The bottom of the container containing the transparent material is coated with a factor that promotes cell attachment and is one among laminin, fibronectin, vitronectin etc.

Wong et al. teach a composition and a method where upon anchor dependent cells can grow, proliferate, differentiate and function on an electrically conductive polymer, wherein said polymer is biocompatible. Said device/ composition comprising electrically conductive biocompatible polymers is applicable to cultivate cells/ cell culture under in-vitro conditions and/or for in-vivo applications to implant cultured cells or the device comprised of electrically conductive biocompatible polymer to heal, prevent cell surgical adhesions, repair tissue or bone defects or replace insufficient or missing cell functions. Wong et al. further teach that Cellular adhesions is enhanced and/or effects on cellular functions, differentiation and proliferation is modulated via first "binding of attachment molecules of specific densities and defined types to the conducting polymers". Subsequently, "the cells are seeded on to or the device is implanted adjacent to the cells that are to be affected". Next voltage in certain range is applied to the polymer in such a way that it brings about the cellular modulation in different cellular parameters stated *supra*. The voltage range is such that it does not damage the cells (abstract, Lines 10-15; Column 2, Lines 43-58). Manifested Modulated cellular parameters of the device/method/composition described *supra* are: e.g., "nerve regeneration, protein absorption and cell adhesion (Column 3, Lines 33-44). Said manifested cellular modulation is measured as a function of voltage applied to the polymer and is governed by the oxidation state of the polymer. Other modulation control factors are: culture conditions, cell type, substrate, polymer type, polymer density as well as density of attachment molecules. The measurement for said manifestation is: e.g., cellular protein production or DNA synthesis in cells that are

seeded on to, or are adjacent to said implanted composition/device (Column 3, Lines 45-58). Wong et al., however, do not clearly teach the physical configuration for said device/composition on which said biocompatible polymer is coated and a method to seed cells on said coating. Casnig teaches said device to be a cell culture plate, wherein bottom of said plate is comprised of optically transparent, electrically conductive coating whereupon cells adhere on the upper side of the plate bottom. Said bottom also has an electrode that is connected to an electrical power source. Cells are cultured on the upper side of said plate bottom under intermittent or continuous electrical field/potential Abstract Lines 1-6). Casnig further cites teachings, wherein electrical fields are applicable to modulate cellular functions (e.g., receptor regulation, cell membrane permeabilization and cell fusion in monolayer cultures; Column 1, Line 60 to Column 2, Line 5). Casnig also teaches methods and devices wherein monolayer adherent cells are cultured on optically transparent electrically conductive coated electrode surfaces and measurement/monitoring changes in said cells upon applying electrical field through the electrodes (Column 3, Line 33 to Column 4, Line 63).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine teachings from Wong et al. et al. with those of Casnig to develop a method to determine the biological activity of a compound by adding said compound to a cell suspended in a vessel containing transparent dielectric material, wherein said vessel is equipped with an electrode to pass voltage through the material and the cell and to collect the optic responses through signals on to an imaging device because Wong et al. a composition and a method where upon anchor dependent cells can grow, proliferate, differentiate and function on an electrically conductive polymer, wherein said polymer is biocompatible and Casnig teaches to culture cells in a device fitted with optically transparent electrically conductive coated electrode surfaces and measure/monitor changes in said cells upon applying electrical field through the electrodes.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Wong et al. et al. according to teachings from Casnig. to obtain the method to determine the bioactive properties of a compound applying the apparatus and the method instantly claimed as is discussed above to apply biocompatible polymer coated compositions/devices and methods to cultivate and monitor a variety of cells and cellular functions under in-vitro and in-vivo conditions were available. In view of the fact that the applicant's invention also recites a composition/ device comprising the same composition and a method to cultivate cells/tissues under both in-vitro and in-vivo conditions on said type of composition/device under an electrical field and to monitor the effect of applied electrical field on said cells comprising the same steps and ingredients as is in the teachings from Examiner-cited prior art.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim Rejections - 35 U.S.C. § 112

12. Following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

13. Claims 3-13, 17-18 and 21-33 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The recitation, "characterizing" in claim 3 is indefinite because it is not clear whether the term includes other ingredients, like the conventional term "comprising", or whether the term excludes other ingredients like the conventional term "consisting of". The term will be read as including other ingredients. Examiner suggests that applicant use the term "having".

All other claims depend directly from the rejected claim (e.g., Claim 3) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Conclusion

14. For reasons aforementioned, no Claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey, can be reached on (571)-272-0775 Monday through Friday 8:30 A.M. to 5:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

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May 23, 2006

K. Srivastava

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